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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/597,866 06/20/00 HELLER

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022249
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HM12/1105

EXAMINER

FORMAN, B

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/597,866

Applicant(s)

HELLER ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-18, and Species A, optical detection, in Paper No. 6 is acknowledged.

Applicant's canceling of non-elected Claims 19-22 is acknowledged.

Claims 1-18 are pending.

Specification

2. The disclosure is objected to because the nucleic acid sequences on page 39 are not identified by a SEQ ID NO.

Appropriate correction is required.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, Applications 08/304,657, filed 09/09/1994; 08/271,882, filed 07/07/1994; and 08/146,504, filed 11/01/1993 do provide adequate support under 35 U.S.C. 112, for claims 10-12 and 14. Additionally, Applications 08/271,882, filed 07/07/1994 and 08/146,504, filed 11/01/1993 do provide adequate support under 35 U.S.C. 112, for claims 5 and 7. Therefore, the effective filing date for instant claims 10-12 and 14 is the filing date of Application 08/534,454 i.e. 09/27/1995 and the effective filing date for instant claims 5 and 6 is the filing date of Application 08/304,657 i.e. 09/09/1994.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-18 are indefinite in Claim 1 for the recitation "biochip having an active area" because "active" is a non-specific functional term and therefore it is unclear how the functional language limits the structural components of the apparatus. It is suggested that Claim 1 be amended to describe the structural limitations e.g. replace "an active" with "a matrix of addressable locations on a surface upon which specific binding entities are attached" (page 8, line 35-page 7, line 5).

b. Claims 1-18 are indefinite in Claim 1 for the recitation "adapted to flow the sample over the active area" because the recitation is functional language but it is unclear how the functional recitation limits the structural components of the apparatus. It is suggested that Claim 1 be amended to recite the structural limitations of the apparatus e.g. replace "adapted" with "comprising a flow cell to" (page 9, lines 26-28).

c. Claim 5 is indefinite for the recitation "adapted to permit radiation from the active area" because the recitation is functional language but it is unclear how the functional recitation limits the structural components of the apparatus. It is suggested that the claim be amended to recite the structural limitations of the apparatus e.g. replace "adapted" with "comprises an aperture" (page 22, lines 35-37).

d. Claim 6 is indefinite for the recitation "ports window" because it is unclear how "ports" further limits the structural limitations of the "window". It is suggested that the claim

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be amended to describe the structural limitations of the "window" as described in the specification e.g. replace "ports" with "flow cell" or "quartz" (page 22, line 37-page 23, line5).

e. Claim 8 is indefinite for the recitation "the flow cell has a volume from substantially 5 to 10 microliters" because it is unclear how "substantially" further limits the flow cell volume. It is suggested that the claim be amended to clarify e.g. replace "substantially" with "about".

f. Claim 14 is indefinite for the recitation "PCMCIA" because the recitation is an acronym, the meaning of which may change over time. It is suggested that the claim be amended to clearly define the invention e.g. recite the full phrase which the acronym represents.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-4, 7 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al. (U.S. Patent No. 5,324,633, filed 22 November 1991). The claims are drawn to an apparatus for the enhanced detection of a biological reaction between a sample and an active area of a biochip. However, the courts have stated that a preamble is generally not accorded any patentable weight where it merely recites the intended use, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone (see *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 481). In the instant case, the preamble is not

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accorded any patentable weight because it merely recites the intended use for the apparatus and because the structural limitations (i.e. biochip and fluidic system) are able to stand alone and are capable of performing the intended use.

Regarding Claim 1, Fodor et al. disclose an apparatus comprising: a biochip having an active area and a fluidic system adapted to flow the sample over the active area of the biochip (Column 12, lines 17-35).

Regarding Claim 2, Fodor et al. disclose the apparatus wherein the fluidic system is in direct contact with the biochip (Column 12, lines 17-35 and Fig. 3c).

Regarding Claim 3, Fodor et al. disclose the apparatus wherein the fluidic system includes a flow cell (Column 12, lines 17-25).

Regarding Claim 4, Fodor et al. disclose the apparatus wherein the flow cell substantially surrounds the active area of the biochip i.e. each flow cell is aligned with an array (Column 12, lines 17-25).

Regarding Claim 7, Fodor et al. disclose the apparatus wherein the flow cell has a defined volume (Column 8, lines 1-13).

Regarding Claim 9, Fodor et al. disclose the apparatus wherein the flow cell further includes an inlet port and an outlet port (Column 8, lines 31-32).

Regarding Claim 10, Fodor et al. disclose the apparatus of Claim 9 further including a reservoir attached to the outlet port (Fig 2, unlabeled reservoir attached to the outlet port #210).

Regarding Claim 11, Fodor et al. disclose the apparatus of Claim 10 further including a waste tube (Fig. 2, unlabeled tube connecting the outlet port #210 to the waste reservoir).

Claim Rejections - 35 USC § 103

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (U.S. Patent No. 5,324,633, filed 22 November 1991) in view of Leland et al. (U.S. Patent No. 6,078,782, filed 7 June 1995).

Regarding Claims 5 and 6, Fodor et al. teach an apparatus comprising: a biochip having an active area and a fluidic system adapted to flow the sample over the active area of the biochip (Column 12, lines 17-35) wherein the flow cell substantially surrounds the active area of the biochip i.e. each flow cell is aligned with an array (Column 12, lines 17-25) and wherein radiation from the biochip is detected external of the apparatus (Column 11, lines 18-60) but they do not teach the flow cell includes a window. Leland et al. teach a similar apparatus comprising a biochip having an active area and a fluidic system adapted to flow the sample over the active area (Column 14, lines 54-64) and further comprising a window (Claim 5) which is a seal-fitted i.e. port (Claim 6) adapted to permit radiation from the active area of the biochip to external of the apparatus (Column 15, lines 13-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the radiation transparent biochip of Fodor et al. with the windowed biochip of Leland et al. wherein the window is seal-fitted (i.e. port) to thereby define the biochip's active area for the expected benefit of detecting emitted radiation exclusively from the active area via the port window as taught by Leland et al. (Column 15, lines 13-15).

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10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (U.S. Patent No. 5,324,633, filed 22 November 1991) in view of Ebersole et al. (U.S. Patent No. 5,658,732, filed 1 March 1995).

Regarding Claim 8, Fodor et al. teach the apparatus wherein the flow cell has a defined volume (Column 8, lines 1-13) but they do not teach the volume from substantially 5 to 10 microliters. However, small hybridization volumes were well known in the art and Ebersole et al. teach a motivation for reducing hybridization volumes i.e. reassociation kinetics are faster and the amount of costly reagents is reduced (Column 13, lines 62-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to minimize the volumes in the apparatus of Fodor et al. and using routine experimentation determine the minimal volumes e.g. 5 to 10 microliters, to thereby optimize experimental results for the known benefits of minimized hybridization volumes i.e. increased speed and efficient use of reagents as taught by Ebersole et al. (Column 13, lines 62-67). It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (U.S. Patent No. 5,324,633, filed 22 November 1991).

Regarding Claim 12, Fodor et al. teach the apparatus of Claim 9 further including a reservoir attached to the outlet port (Fig 2, unlabeled reservoir attached to the outlet port #210) but they do not teach the reservoir is expandable. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reservoir of Fodor et al. by providing an expandable reservoir which expands to collect solutions flushed

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from the active area to thereby eliminate the need to empty the reservoir during multiple wash steps for the obvious benefit of optimizing experimental time and labor. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

12. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (U.S. Patent No. 5,324,633, filed 22 November 1991) in view of Hollis et al. (U.S. Patent No. 5,846,708, filed 23 April 1992).

Regarding Claim 13, Fodor et al. teach an apparatus comprising: a biochip having an active area and a fluidic system adapted to flow the sample over the active area of the biochip (Column 12, lines 17-35) wherein a biological reaction between a sample and an active area is detected (Column 12, lines 37-44) but they do not teach the apparatus wherein the biochip is disposed on a circuit board. Hollis et al. teach a similar apparatus comprising a biochip and a fluidic system wherein the biochip is disposed on a circuit board (Column 14, lines 49-65) wherein the circuit board facilitates rapid detection of biological reactions and reduces costs (Column 19, lines 38-44). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the biochip of Fodor et al. by including the circuit board as taught by Hollis et al. to thereby facilitate rapid detection and reduce costs of detection of the biological reaction for the expected benefit of speed and economy of detection as taught by Hollis et al. (Column 19, lines 38-44).

Regarding Claim 14, Hollis et al. do not teach the circuit board is a PCMCIA board. However, The courts have stated that the greater the physical similarities between the claimed

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species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify circuit board of Hollis et al. with the claimed PCMCIA board based on the functional and physical similarities between the PCMCIA board and circuit board of Hollis et al.

Regarding Claim 15, Hollis et al. teach the circuit board further including wires connecting the biochip to the circuit board (Column 4, lines 23-31 and Fig. 1).

Regarding Claim 16, Hollis et al. teach the circuit board is a printed circuit board i.e. semiconductor chip (Column 4, lines 28-31).

Regarding Claim 17, Hollis et al. teach the circuit board wherein the wires are embedded in a protective material i.e. semiconductor or dielectric material (Column 14, lines 42-48).

Regarding Claim 18, Hollis et al. do not teach the protective material comprises ultraviolet light resistant epoxy. However, The courts have stated that the greater the physical and functional similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify protective material of Hollis et al. with the claimed ultraviolet resistant epoxy based on the functional and physical similarities (i.e. UV resistance) between the claimed ultraviolet resistant epoxy and the semiconductor and dielectric material of Hollis et al.

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Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
November 1, 2001



W. Gary Jones
Supervisory Patent Examiner
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